EMA/413459/2020

European Medicines Agency decision

P/0305/2020

of 12 August 2020

on the acceptance of a modification of an agreed paediatric investigation plan for reslizumab (Cinqaero), (EMEA-001202-PIP02-13-M04) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Only the English text is authentic.

European Medicines Agency decision

P/0305/2020

of 12 August 2020

on the acceptance of a modification of an agreed paediatric investigation plan for reslizumab (Cinqaero), (EMEA-001202-PIP02-13-M04) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0017/2015 issued on 30 January 2015, the decision P/0256/2016 issued on 5 October 2016, the decision P/0010/2018 issued on 30 January 2018 and the decision P/0284/2019 issued on 30 September 2019,

Having regard to the application submitted by Teva Pharmaceuticals Europe on 23 March 2020 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver and proposing a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 26 June 2020, in accordance with Article 22 of Regulation (EC) No 1901/2006 and Article 13 of said Regulation,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan and to the deferral and to the waiver.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral and to the waiver.

(3) It is therefore appropriate to adopt a decision granting a waiver.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for reslizumab, concentrate for solution for infusion, solution for injection, intravenous use, subcutaneous use, including changes to the deferral and to the waiver, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

A waiver for reslizumab, concentrate for solution for infusion, solution for injection, intravenous use, subcutaneous use, including changes to the deferral and to the waiver, the details of which are set out in the opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Teva Pharmaceuticals Europe, Field House, Station Approach, CM20 2FB – Harlow, United Kingdom.

EMA/PDCO/192222/2020
Amsterdam, 26 June 2020

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan and on the granting of a product-specific waiver

EMEA-001202-PIP02-13-M04

Scope of the application

Active substance(s):

Reslizumab

Invented name:

Cinqaero

Condition(s):

Treatment of asthma

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Concentrate for solution for infusion

Solution for injection

Route(s) of administration:

Intravenous use

Subcutaneous use

Name/corporate name of the PIP applicant:

Teva Pharmaceuticals Europe

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Teva Pharmaceuticals Europe submitted to the European Medicines Agency on 23 March 2020 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0017/2015 issued on 30 January 2015, the decision P/0256/2016 issued on 5 October 2016, the decision P/0010/2018 issued on 30 January 2018 and the decision P/0284/2019 issued on 30 September 2019.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral and changes to the waiver to cover the remaining subsets of the paediatric population.

The procedure started on 30 April 2020.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

The waiver has been extended to cover all subsets of the paediatric population.

Opinion

The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to agree to changes to the paediatric investigation plan and to amend the scope of the waiver in accordance with Article 11(1)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population as set out in Annex I of this opinion.

The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition:

Treatment of asthma

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- concentrate for solution for infusion, solution for injection, intravenous use, subcutaneous use;
- on the grounds that the specific medicinal product is likely to be ineffective.

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of asthma

Authorised indication(s):

- CINQAERO is indicated as add-on therapy in adult patients with severe eosinophilic asthma inadequately controlled despite high-dose inhaled corticosteroids plus another medicinal product for maintenance treatment.

Authorised pharmaceutical form(s):

Concentrate for solution for infusion

Authorised route(s) of administration:

Intravenous use